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support group)

Certified: Accreditation Council  
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Clinical Instructor: Department  
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University of New Mexico

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November 11, 1999

Paula S. McKeever  
Center for **Biologics** Evaluation and Research  
Food and Drug Administration  
1401 Rockville Pike, Suite 200N  
Rockville, Maryland 20852-1448

Dear Ms. McKeever:

I recently had an opportunity to review the proposed rules from September 30, 1999, Volume 64, #189 as pertains to proposed regulations for fertility clinics in the United States. After review of these, there are two areas of concern.

The first concern that I have is that it seems to me that in reproductive work, at least, the risk of transmissible spongiform encephalopathies (**TSE**) including **Creutzfeldt-Jakob** disease (CJD) would be a very rare mode of transmission via sperm or oocytes and that this would be extraneous testing.

Of greater concern is the fact that if we are forced to freeze embryos then the success rates for donor embryos will probably drop **from** a rate of 50% or greater to 10% or less because of the inability of embryos to withstand the freeze thaw **freeze** process. This would be devastating given that these cycles often cost in the range of \$10,000 to \$12,000 us.

While there is a risk of transmissible diseases with fresh embryos, with careful screening, hopefully this risk can be kept to a minimum and I am unsure nationally as to how many cases of transmission of diseases have occurred via this route.

Again, many thanks for hearing our suggestions in regard to the proposed regulations.

Yours sincerely,

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President Southwest Fertility Services, P.C.  
NAA:kms

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